

Exempt Review

1.0 Purpose

To describe the policies and procedures for the Wright State University (WSU) exempt review process.

2.0 Scope

This policy applies to all human subject research that is conducted by Wright State University faculty, staff and students and human subject research for which the WSU Institutional Review Board (hereafter referred to as IRB) acts as the IRB of record for an external entity (e.g., Premier Hospitals, Dayton VAMC).

Federal and institutional requirements do not allow WSU investigators to rely on an exempt determination made by external IRB. Local exempt review and determination via this policy is required.

***This policy does not apply to exemptions granted prior to January 21, 2019. Those studies were determined to be exempt per 45 CFR 45.101(b) and 21 CFR 56.104(d) and relevant institutional policy.*

3.0 Definitions

3.1 **Investigator** means the Project Director/Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposing of research, including persons who are subcontractors, collaborators or consultants. At WSU this definition includes, but is not limited to, the following roles: Principal investigator, co-investigators, research coordinators, research associates, collaborators and consultants, and may include research assistants and students as identified by the PD/PI depending on their specific roles and responsibilities.

3.2 **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:

3.2.1 Obtains information or biospecimens through intervention or interaction with the individual and uses, studies or analyzes the information or biospecimens; or

3.2.2 Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable specimens.

- 3.3 **Intervention** means both the physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- 3.4 **Interaction** means communication or interpersonal contact between investigator and subject.
- 3.5 **Private information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- 3.6 **Identifiable private information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information
- 3.7 **Identifiable biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- 3.8 **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- 3.9 **Written, or in writing** means writing on a tangible medium (e.g., paper) or in an electronic format.
- 3.10 **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are **deemed not to be research**:
- 3.10.1 Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- 3.10.2 Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated

with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

- 3.10.3 Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- 3.10.4 Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

4.0 Policy

The Department of Health and Human Services (DHHS) and FDA regulations apply to research involving human subjects, but there are some categories of research that the regulations consider to be exempt from IRB review requirements. To qualify as an exempt study, the research must fall within one of the specific federal regulatory categories AND satisfy the other regulatory and WSU institutional requirements.

Investigators cannot self-determine whether a study is exempt. A determination of exemption must be made by the WSU designee (e.g., IRB staff). To request a determination an investigator must complete and submit the Initial Review Application in the WSU IRB electronic submission system (i.e., InfoED).

It is important to understand that although the research may qualify as exempt from IRB review, it must still be conducted in accordance with the institutional ethical standards, including:

- 4.1 Equitable selection of subjects
- 4.2 Adequate provisions to maintain confidentiality of any identifiable information collected.
- 4.3 Adequate provisions to protect subject privacy.
- 4.4 Present minimal risk to subjects.

Investigator activities that clearly **do not meet both** the definition of human subject and research as defined in Section 3.0 above are not required to be submit for review under this policy. However, if an investigator is unsure or requires a written “Not Human Subjects Research” determination, he/she should consult with the WSU IRB Office or submit an initial application for review.

5.0 Procedures

5.1 Exempt Categories

The DHHS exempt categories will be applied to proposed research regardless of funding source, unless one or more of the exceptions described in Section 5.2 apply. The categories defined in 45 CFR 46.104(d) are as follows:

Category 1:

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2:

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if **at least one of the following criteria is met:**

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Category 3:

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and **at least one of the following criteria is met:**

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Category 4:

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if **at least one of the following criteria is met:**

- (i) The identifiable private information or identifiable biospecimens are publicly available;
- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through

identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

- (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
- (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Category 5:

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or

supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Category 6:

Taste and food quality evaluation and consumer acceptance studies:

- (i) If wholesome foods without additives are consumed, or
- (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Category 7:

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

Category 8:

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;
- (iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
- (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

5.2 Exceptions

5.2.1 Broad Consent

The use of broad consent as described in Category 7 (45 CFR 46.104(d)(7)) and Category 8 (45 CFR 46.104(d)(8)) is not permissible under this policy. Therefore, WSU will not exempt studies under those categories.

5.2.2 FDA-Regulated Research

Research is subject to FDA regulation if it involves a drug, medical device, food, or other product regulated by the FDA. The FDA only provides three types of exemption:

- 5.2.2.1 Research which started before July 27, 1981, and either did not require FDA approval before that date, or, was subject to requirements for IRB review prior to that date, and remains subject to review by an IRB which meets FDA requirements;
- 5.2.2.2 Emergency use of a test article, provided any such use is reported to the WSU IRB in accordance with the [Research Involving Medical Devices Policy](#)
- 5.2.2.3 The taste and food quality evaluation provided for above in category 6.

Any other research subject to FDA regulation cannot be exempt.

5.2.3 Prisoners

DHHS regulations and WSU prohibit the conduct of research involving prisoners from receiving exempt review except for research aimed at involving a broader subject population that **only incidentally** includes prisoners.

5.2.4 Children

Research involving children (individuals less than 18 years of age) cannot be exempted under Category 2 (except for educational tests or observation of public behavior when investigators do not participate in activities being observed) or Category 3. This does not mean that this type of research is prohibited. It means that it must receive IRB review and approval (i.e., expedited or full).

5.3 Informed Consent and HIPAA Authorization Requirements

Written informed consent is not required for research determined to be exempt from IRB review. However, the IRB encourages investigators to provide potential subjects with information about the study (e.g., informational letter) whenever feasible prior to engaging any subject in that research as a way to support their voluntary participation.

If the proposed exempt research involves utilization of Protected Health Information (PHI), HIPAA regulations apply. Investigators must indicate whether the research involves PHI as part of the initial application process and justify a waiver of authorization if written authorization will not be obtained from each subject in accordance with the Privacy Rule (see [Human Subject Research Use and Disclosure of Protected Health Information Policy](#) for more information about waivers).

5.4 WSU IRB Office Review

WSU IRB staff members (IRB staff) are responsible for screening new studies to determine whether or not the proposed research requires IRB review or qualifies for an exempt determination. An IRB staff member has the authority to make an exempt determination (unless limited IRB is required – see Section 5.5 below) but may consult with the IRB Chair or an IRB member if he/she needs assistance in determining whether or not the proposed research is exempt.

After a study has been determined to be exempt, the IRB staff member will generate and send an exemption letter via InfoED. This letter must document the date that exemption was made, the applicable exemption category or categories, and limited IRB review, when applicable.

5.5 Limited IRB Review

Limited IRB member review and approval of the proposed privacy and confidentiality provisions is required when research meets the exemption criteria defined for 45 CFR 46.104(d)(2)iii) or 45 CFR 46.104(d)(3)(i)C).

In such cases, where limited IRB is required, the IRB staff will assign a voting IRB member to review the submission in InfoED. It is important to note that the IRB

member's review is limited to the privacy and confidentiality provisions and does not include approval of all normal review criteria defined at 45 CFR 46.111.

Limited IRB review and approval must be documented in the exemption letter when applicable.

5.6 Continuing Review, Study Closure, Required Amendments

Research that is determined to be exempt does not require continuing review; however, in the interests of keeping the WSU IRB files current, exempt research will automatically be given a 3-year expiration date.

Sixty (60) days prior to the expiration date, an email notification will be sent to the Principal Investigator (PI) as a reminder to request an extension of the exemption period, if needed. To extend the exemption period, the PI will be asked to complete and submit the Continuing Review Form. If the PI does not request an extension, the exemption will close on the expiration date. After such closure, the PI would be required to submit a new application for an exemption determination in order to continue the research.

If the **exempt research involves protected health information (PHI)**, the PI is required to submit an amendment to his/her application via InfoED prior to any study staff changes and/or study data collection changes (e.g., collection of additional data points, increase in number of subject records or biospecimens to be involved).

The IRB staff will review the amendment and send a written letter approving the change via administrative review, if appropriate.

If the **exempt research does not involve PHI**, amendments are not required. However, the PI must consult with an IRB staff member prior to making any substantive changes to the initial research plan that received the exemption to determine whether the modified research plan remains exempt.

5.7 Other Institutional Reviews

It is important to understand that research that is determined to be exempt from IRB review, may still require other institutional reviews and approvals (e.g., affiliated hospital, department, etc....) before being allowed to commence. The investigator is responsible for identifying and completing all review requirements prior to the initiation of research.



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Exempt Review
Approved By: WSU IRB Working
Group
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6.0 Responsibilities and Authorities

6.1 Investigators

All investigators must read and understand this policy and conduct exempt research in accordance with ethical norms.

6.2 WSU IRB

The WSU IRB is responsible for maintaining this policy and ensuring the exempt review procedure is compliant and well supported.

7.0 Records

All records related to this process will be stored and maintained in accordance with any WSU policy, federal regulations and sponsor requirements associated with the human subject research protocol under review.

8.0 References

- 8.1 45 CFR 46.104
- 8.2 21 CFR 56.104
- 8.3 VHA Handbook
- 8.4 38 CFR 16